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April 15, 2015

Via Federal Express
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Isolated Chicken Eye Test

Dear Section 8(e) Coordinator:

[redacted] is submitting results of a Isolated Chicken Eye Test (ICE) with [redacted] bromide dihydrochloride, conducted by [redacted]. The test substance is used as a cosmetic ingredient.

The test substance was evaluated for eye irritation potential in the Isolated Chicken Eye (ICE) test. Chicken eyes were obtained from slaughter animals used for human consumption. The isolated chicken eyes were exposed to a single application of 30 µL (liquids) or 30 mg (solids) for 10 seconds followed by a 20 mL saline rinse. Three main parameters were measured to disclose possible adverse eye effects: corneal thickness (expressed as corneal swelling), corneal opacity and fluorescein retention of damaged epithelial cells. In addition, histopathology of the corneas was performed.

The test substance caused corneal effects consisting of slight corneal swelling (mean of 9%), moderate/severe opacity (mean score 3.0) and moderate/severe fluorescein retention (mean score 3.0). The severe opacity and severe fluorescein retention were observed as spots. In addition, red/violet staining of cornea and sclera (massive) was observed which persisted during the observation period.

Microscopic examination of the corneas treated with the test substance revealed slight erosion and moderate vacuolation (top area) of the epithelium, and the epithelium partly detached from the basement membrane (one cornea).

The negative control eye did not show any corneal effect and demonstrated that the general conditions during the tests were adequate.

The positive control NaOH caused (very) severe corneal effects and demonstrated the ICE test valid to detect severe eye irritants.

Microscopic examination of the cornea treated with the negative control (saline) did not reveal any abnormalities. The positive control NaOH caused severe erosion of the epithelium, pyknotic nuclei in the inner region of the stroma and necrosis of the endothelium.

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Applying the classification criteria of the ICE, the following irritation classifications can be assigned to the test substance: Category 1: irreversible effects on the eye/serious damage to the eye" (UN-GHS and EU-CLP classifications).

[redacted] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,